UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF VIRGINIA
RICHMOND DIVISION

ANGELA MONEYMAKER, Plaintiff, v. HOWMEDICA OSTEONICS CORP., Defendant.	Case No.: 3:15-cv-00029-JAG

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANT HOWMEDICA OSTEONICS CORP.'S MOTION TO DISMISS FIRST AMENDED COMPLAINT

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PRELIMINARY STATEMENT

This case involves various claims arising from the implantation of an investigational spinal implant known as the CerviCore™ Intervertebral Disc ("CerviCore™"). The CerviCore™ was a state of the art total disc replacement system that was under investigation as a potential alternative to spinal fusion surgery. This investigational device was approved by the United States Food and Drug Administration ("FDA") for use in a clinical trial to measure the safety and effectiveness of the device.[1]

The FDA has classified intervertebral prosthetic disc devices such as the CerviCore™ as Class III medical devices.[2] Class III classification is limited to the most complex and technologically advanced devices that present true innovation but also present risk of injury or illness and are important to sustaining life or health. See Riegel v. Medtronic, Inc., 128 S. Ct. 999, 1003 (2008). A very select subset of Class III devices -- only about 1% -- undergo the premarket approval ("PMA") process, which is the most rigorous FDA approval process. See id. The United States Supreme Court has held that as to Class III devices that have undergone the rigorous PMA process, most products liability claims are expressly preempted by the Medical Device Amendments of 1976 ("MDA"), 21 U.S.C. § 360k, to the Federal Food, Drug and Cosmetics Act ("FDCA"). See Riegel, 128 S. Ct. 999. Investigational devices, like the CerviCore™, which have been approved for an Investigational Device Exemption ("IDE"), undergo an investigational process that is at least as rigorous as the PMA process, and, thus, the body of preemption law governing PMA devices applies equally to IDE devices. See Martin v. Telectronics Pacing Systems, Inc., 105 F.3d 1090 (6th Cir. 1997); Gile v. Optical Radiation Corp., 22 F.3d 540 (3rd Cir. 1994). As the claims alleged in this action directly challenge the

[1] See FDA's "Guidance Document for the Preparation of IDEs for Spinal Systems", available at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073771.htm. Public records and documents incorporated into the complaint by reference are subject to judicial notice, and may be properly considered on a motion to dismiss. See Tellabs, Inc. v. Makor Issues & Rights, Ltd., 127 S. Ct. 2499, 2509 (2007).

[2] See http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=4136.

safety and effectiveness of the CerviCore™, the claims must be dismissed because each of Plaintiff Angela Moneymaker's claims are expressly preempted by the MDA pursuant to Riegel.

Yet even if Plaintiff arguably stated a parallel claim sufficient to withstand express preemption by the MDA, her claims must still be dismissed as the statute of limitations expired with regard to each of Plaintiff's causes of action. The allegations in the First Amended Complaint ("FAC") show that the statute of limitations accrued no later than July 2006, due to the shifting and subsequent removal of the device in or about June 2006 and Plaintiff's physician's reporting of the shifting of the device to the FDA's MAUDE database in July 2006.

Additionally, Plaintiff's three strict liability claims require dismissal, as Virginia does not recognize such causes of action. Finally, Plaintiff's claims for fraud by concealment, fraudulent misrepresentation, negligent misrepresentation, and breach of implied warranty must be dismissed for failure to adequately plead these causes of action.

Accordingly, Plaintiff's FAC must be dismissed in its entirety for failure to state a claim upon which relief can be granted, pursuant to Federal Rule of Civil Procedure 12(b)(6).

BACKGROUND

A. Plaintiff Angela Moneymaker

On or about April 11, 2014, Plaintiff filed her original Complaint, and later filed the FAC on or about April 1, 2015. Plaintiff alleges that she received a CerviCore™[3] in May or June 2006, which "shifted" approximately six weeks later and required "immediate[] … removal surgery." (FAC at ¶ 155-156.) Plaintiff further alleges that her physician, Dr. Young, "reported the adverse event to the FDA's MAUDE … database" on July 6, 2006. (Id. at ¶ 157 (citing https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/detail.cfm?mdrfoi_id=739251).) Plaintiff then alleges that she "still suffers from [CerviCore™'s] effects", including nerve damage, increased neck pain, numbness in her arm, headaches, and spinal bone damage. (Id. at

[3] The CerviCore™ was an IDE device that was approved by the FDA for use in a clinical study to measure the device's safety and effectiveness. It, thus, underwent the FDA's exacting and comprehensive IDE application process, and entered the clinical trial stage. The purpose of the IDE and clinical trial of the CerviCore™ was to gather data on safety and effectiveness for an eventual PMA application. However, HOC ultimately elected to discontinue the clinical study.

¶¶ 158-161.) Based upon these claims, Plaintiff has asserted causes of action against defendant Howmedica Osteonics Corp. ("HOC") for design defect (Count I), manufacturing defect (Count II), failure to warn (Count III), negligence (Count IV), gross negligence (Count V), fraud by concealment (Count VI), fraudulent misrepresentation (Count VII), negligent misrepresentation (Count VIII), breach of contract (Count IX), breach of express warranty (Count X), breach of implied warranty (Count XI), infliction of emotion distress (Count XII), Virginia statutory and common law remedies (Count XIII), and punitive damages.

B. The FDA's Rigorous PMA and IDE Processes

The FDA's regulatory regime has established "various levels of oversight for medical devices, depending on the risks they present." Riegel, 128 S. Ct. at 1003. Under the MDA[4], medical devices are placed into one of three "classes". Class III devices, including intervertebral disc prostheses such as the CerviCore™, "receiv[e] the most federal oversight" because they "'present[] a potential unreasonable risk of illness or injury'" or are "'for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health.'" Id. (quoting 21 U.S.C. § 360c(a)(1)(C)(ii)).

1. The PMA Process

Of the Class III devices, only a very small subset undergo the "rigorous regime" of the PMA process. See Riegel, 128 S. Ct. at 1004 (explaining that in 2005, the FDA approved 3,148 devices through the § 510(k) premarket notification process, but only 32 devices through the rigorous PMA process). Pursuant to the MDA, the FDA has promulgated numerous regulations that delineate PMA requirements for Class III medical devices. See Buckman Co. v. Pl.'s Legal Comm., 121 S. Ct. 1012 (2001). These regulations require a PMA application to include comprehensive data from which the FDA can make a reasoned determination of the device's safety and efficacy, including human clinical trials, design specifications, manufacturing processes and quality controls, and proposed labeling and advertising. See 21 C.F.R. § 814.20; Riegel, 128 S. Ct. at 1004 (citing 21 U.S.C. §§ 360c(a)(2)(B), 360e(d)(1)(A))). The PMA

[4] In 1976, Congress enacted the MDA, which expanded the FDA's authority to regulate medical devices. See Riegel, 128 S. Ct. at 1002-03.

process requires the manufacturer to submit extensive information, and the "FDA spends an average of 1,200 hours reviewing each application." Riegel, 128 S. Ct. at 1004. The FDA "grants premarket approval only if it finds there is a 'reasonable assurance' of the device's 'safety and effectiveness.'" Id. (citing 21 U.S.C. § 360e(d)). Notably, the FDA retains control of a PMA medical device even *after* granting approval and throughout the life of the device. Riegel, 128 S. Ct. at 1005 (citing 21 U.S.C. § 360e(d)(6)).

2. The Investigational Device Exemption to the PMA Process

An IDE allows experimental devices to be used in clinical studies to determine their safety and effectiveness. Safety and effectiveness data may be used to support an eventual application for FDA approval, most often pursuant to the PMA process. "In enacting the MDA, Congress recognized the need for special treatment of investigational devices which, by their very nature, could not meet the requirements applicable to marketed devices." Gile, 22 F.3d at 542.[5] As explained by the Sixth Circuit in an action involving preemption of an IDE device:

> To obtain approval of a device under the IDE, a manufacturer must submit an application to the FDA containing an abundance of information. Pursuant to 21 C.F.R. § 812.20, the manufacturer must submit an application setting forth a complete report of all prior investigations and a "description of the methods, facilities, and controls used for the manufacture, processing, packing, storage, and where appropriate, installation of the device, in sufficient detail so that a person generally familiar with good manufacturing practices can made [sic] a knowledgeable judgment about the quality control used in the manufacture of the device." 21 C.F.R. § 812.20.
>
> Pursuant to 21 C.F.R. § 812.25, the manufacturer must submit a detailed statement regarding the intended use of the device and the objectives and planned duration of the investigational study; a written protocol describing the methodology to be used and an analysis of the protocol demonstrating that the investigation is scientifically sound; an analysis of all risks involved; a description of each component, ingredient, property, and principle of operation of the device; a detailed description of the methods, facilities and

[5] The IDE was established "to encourage, to the extent consistent with the protection of the public health and safety and with ethical standards, the discovery and development of useful devices intended for human use and to that end to maintain optimum freedom for scientific investigators in their pursuit of that purpose." 21 U.S.C. § 360j(g)(1).

> controls used for manufacturing, processing, packing, storing and installing the device; sample agreements between the manufacturers and all proposed investigators; detailed information about the health care professionals and institutions participating in the investigation; proposed labeling; proposed informed consent forms; and a full set of written procedures for monitoring the investigation, including record and report maintenance. Pursuant to 21 C.F.R. § 812.27, the manufacturer must submit a bibliography of every publication relevant to the evaluation of the device and information from non-clinical testing.

Martin, 105 F.3d at 1095.

Following FDA approval for a clinical study, IDE devices remain under the FDA's supervision both during and after the clinical trial process, and the FDA "imposes strict requirements regarding design, manufacture, and safety [which preempt] states from passing laws, whether court or legislature initiated, affecting such requirements." Burgos v. Satiety, Inc., 2010 U.S. Dist. LEXIS 125924, at *5-6 (E.D.N.Y. Nov. 30, 2010) (quotations omitted); see also 21 C.F.R. § 812 (imposing over 150 separately numbered regulations on IDE devices).

As demonstrated below, courts have applied, and continue to apply, the same preemption analysis used in cases involving PMA devices to cases involving IDE devices, finding that state law products liability claims in connection with IDE devices are preempted under the MDA. See, e.g., Martin, 105 F.3d 1090; Gile, 22 F.3d 540.

ARGUMENT

To survive a motion to dismiss pursuant to Rule 12(b)(6), a complaint must allege "enough facts to state a claim to relief that is plausible on its face." Bell Atlantic Corp. v. Twombly, 127 S. Ct. 1955, 1974 (2007). "[A] plaintiff's obligation to provide the grounds of his entitle[ment] to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do … Factual allegations must be enough to raise a right to relief above the speculative level." Id. at 1964-65 (internal quotations omitted). Those factual allegations must "nudge[] [the] claims across the line from conceivable to plausible...." Id. at 1975. Indeed, a plaintiff may not fashion a complaint with "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements." Ashcroft v. Iqbal, 129 S. Ct. 1937, 1949-50 (2009). "Judgment should be entered when the pleadings … fail to state any

cognizable claim for relief, and the matter can, therefore, be decided as a matter of law." Harmon v. DynCorp Int'l, Inc., 2015 U.S. Dist. LEXIS 14604, at *20 (E.D. Va. Feb. 6, 2015 (quotation omitted). Moreover, "[a] complaint should be dismissed 'when the face of the complaint clearly reveals the existence of a meritorious affirmative defense.'" Craddock v. Beneficial Fin. I, Inc., 2014 U.S. Dist. LEXIS 124290, at *4 (W.D. Va. Sept. 4, 2014) (quoting Brockington v. Boykins, 637 F.3d 503, 506 (4th Cir. 2011)).

With regard to fraud and fraud-related claims, Rule 9(b) imposes a "heightened pleading" standard, requiring a complaint to "'state with particularity the circumstances constituting the fraud.'" Ali v. Allergan USA, Inc., 2012 U.S. Dist. LEXIS 121417, at *15 (E.D. Va. Aug. 23, 2012) (quoting Fed. R. Civ. P. 9(b)). "[T]he 'circumstances' required to be pled with particularity … are the time, place, and contents of the false representations, as well as the identity of the person making the misrepresentation and what he obtained thereby." Harrison v. Westinghouse Savannah River Co., 176 F.3d 776, 784 (4th Cir. 1999) (quotations omitted).

I. THE MDA PREEMPTS CLAIMS CHALLENGING THE SAFETY AND EFFECTIVENESS OF IDE DEVICES

The United States Supreme Court has held that the very small number of Class III devices approved pursuant to the FDA's exacting and comprehensive PMA process are exempt from all claims that impose requirements that are different from, or in addition to, the FDA's requirements. See Riegel, 128 S. Ct. at 1007, 1011. The Court found that the MDA's express preemption clause "bars common-law claims challenging the safety and effectiveness of a medical device given premarket approval by the [FDA]." Id. at 1002. The Court instructed that the MDA preempts products liability claims, including such claims for failure to warn, defective design, negligence, and breach of implied warranty.[6] See id. at 1006-07.

[6] Many courts around the country -- including the Fourth Circuit, this very Court, and other courts within the Fourth Circuit -- have recognized the clear holding of Riegel in other actions involving medical devices. See, e.g., Walker v. Medtronic, Inc., 670 F.3d 569 (4th Cir. 2012) (affirming dismissal of state law claims regarding a PMA device as preempted by MDA); Ali, 2012 U.S. Dist. LEXIS 121417 (dismissing claims as expressly preempted by the MDA); Adkins v. Cytyc Corp., 2008 U.S. Dist. LEXIS 123843 (W.D. Va. Jul. 3, 2008) (same).

The Supreme Court reached its conclusion in Riegel in reliance on the MDA's express preemption provision, which mandates "that no State 'may establish or continue in effect with respect to a device … any requirement' relating to safety or effectiveness that is different from, or in addition to, federal requirements." Riegel, 128 S. Ct. at 1010 (citing 21 U.S.C. § 360k(a))) (emphasis omitted). The Court acknowledged that Congress enacted this express preemption provision to prevent states from imposing additional or different medical device requirements, whether directly or through products liability litigation. See 21 U.S.C. § 360k(a); see generally Riegel, 128 S. Ct. at 1006, 1010. The Supreme Court found that the PMA process imposes device-specific requirements relating to safety and effectiveness. See Riegel, 128 S. Ct. at 1007.

Similarly, courts have long held that the MDA's express preemption provision applies equally to IDE devices because they are subject to a level of FDA oversight and control that is at least equivalent to PMA devices. See Martin, 105 F.3d 1090; Becker v. Optical Radiation Corp., 66 F.3d 18, 21 (2nd Cir. 1995); Gile, 22 F.3d 540; Berish v. Richards Medical Co., 928 F. Supp. 185, 190 (N.D.N.Y. 1996). For example, in Martin, the Sixth Circuit observed:

> Unlike the general federal requirements discussed in Medtronic, the regulations governing investigational devices are essentially device specific. There are no specific regulations governing pacemakers like the one at issue; however, the application and approval process under the IDE is device specific. For example, the FDA requires information regarding "the methods, facilities, and controls used for manufacture … of the device, in sufficient detail so that a person generally familiar with good manufacturing practices can make a knowledgeable judgment about the quality control used in the manufacture of the device." 21 C.F.R. § 812.20(b)(3). The FDA then exempts the device, if approved, from the general requirements of good manufacturing practice that would ordinarily apply. 21 C.F.R. § 812.1(a). In reviewing the application, the FDA calculates the risks and benefits of the particular device and grants an exemption only if the risks are outweighed by the benefits to the subjects. 21 C.F.R. § 812.30(b)(4).

105 F.3d at 1097.

Additionally, in Gile, the Third Circuit found that state court claims against an investigational device, like that alleged in the present case, ran against the countervailing public policy of discovery and development of new products. The Court stated:

> "[I]f experimental procedures are subject to hindsight evaluation by juries, so that failed experiments threaten to impose enormous tort liability on the experimenter, there will be fewer experimental treatments, and patients will suffer." Thus, state tort claims run counter to the important public policy, recognized by Congress, of promoting scientific inventions.

Gile, 22 F.3d at 546 (quoting Slater v. Optical Radiation Corp., 961 F.2d 1330, 1334 (7th Cir. 1992)). More recently, and since the Supreme Court's decision in Riegel, the Eastern District of New York specifically held that "[b]ecause IDE devices are subject to a level of FDA oversight and control that is, for the purpose of a preemption analysis, identical to that governing PMA devices, the body of preemption law governing PMA devices applies equally to [IDE devices]." Burgos, 2010 U.S. Dist. LEXIS 125924 at *6.

A. Plaintiff's Claims for Strict Liability, Negligence, and Breach of Implied Warranty Are Preempted By the MDA.

The MDA's express preemption provision unequivocally applies to the CerviCore™ and state law claims challenging the safety and effectiveness of the CerviCore™. In the present case, Plaintiff's state law claims impose different or additional requirements on this IDE device, which are expressly prohibited by the MDA. See Riegel, 128 S. Ct. at 1007. Specifically, the crux of Plaintiff's claims is that the CerviCore™ failed in some manner, which allegedly caused her injury. (See FAC at ¶¶ 179-227, 252-258.) As in Riegel, Plaintiff's claims are expressly preempted because they assert "general tort duties of care," allege that "a device was designed, labeled, or manufactured in an unsafe or ineffective manner," and impose different or additional requirements related to the safety and effectiveness of the CerviCore™. See Riegel, 128 S. Ct. at 1010. In other words, these claims fall squarely into the MDA's express preemption provision.

1. Strict Liability Claims Are Expressly Preempted.

Courts have noted that IDE manufacturing defect claims are expressly preempted:

> To allow a cause of action for a manufacturing defect under state law where the FDA has specifically exempted an investigational

> device from Good Manufacturing regulations would thwart the goals of the IDE exemption "to encourage, to the extent consistent with the protection of public health and safety and with ethical standards, the discovery and development of useful devices intended for human use."

Martin, 105 F.3d at 1099 (quoting 21 U.S.C. § 360j(g)).[7] The manufacturing defect claim here is a state law claim regarding the safety and effectiveness of the device that alleges violations of inapplicable Current Good Manufacturing Practices ("CGMPs"). (See FAC at ¶¶ 66-69, 197.)

Design defect claims are also preempted: "to allow a cause of action for design defect where the FDA has specifically approved of the design of the device for investigational purposes would thwart the goals of safety and innovation." Martin, 105 F.3d at 1099. Indeed, logically, it is impossible to maintain a design defect claim on the grounds that the design is unreasonably dangerous because an IDE device is experimental: "[T]he FDA can hardly be expected to specify the safe and effective design of a device when it is still experimental. The point of the experiment is to find out *whether* the design is safe and effective." Becker, 66 F.3d at 21 (emphasis in original); accord Gile, 22 F.3d at 544-45; Slater, 961 F.2d at 1333.[8] Yet, Plaintiff improperly pursues a design defect claim that merely alleges that the design of the CerviCore™ was unreasonably dangerous and fails to set forth *any* allegations -- much less "concrete allegations" -- that the design of the CerviCore™ implanted in Plaintiff was not the design at issue in the IDE. (See FAC at ¶¶ 60-65, 183.)

Failure to warn claims are likewise preempted by the MDA, as they "would impede the implementation and enforcement of specific federal requirements…[and] would impose different requirements or requirements in addition to those required by federal regulations. Such requirements would impede Congress' intent in enacting the investigational device exemption to promote the development of medical devices for human use to the extent consistent with safety

[7] Cf. In re Medtronic, Inc. Sprint Fidelis Leads Prods. Liab. Litig., 623 F.3d 1200, 1207 (8th Cir. 2010) ("manufacturing defect claims are not parallel....").

[8] Cf. In re Medtronic, 623 F.3d at 1206 ("[a]bsent concrete allegations that the product sold … was not the product design approved in the PMA", design defect claims "are expressly preempted by § 360k").

to human life." Martin, 105 F.3d at 1100.[9] Plaintiff's failure to warn claim is a straightforward state law claim alleging a failure to "properly label, market, and warn human study subjects and/or their physicians of [the device's] risks and adverse events", such as risks that "its design caused excessive wear", among a laundry list of others. (See FAC at ¶¶ 208-209.)

2. Breach of Implied Warranty Claims are Expressly Preempted.

In Riegel, the Supreme Court explicitly held that breach of implied warranty claims are expressly preempted by the MDA. "[F]or plaintiff to succeed on her [implied warranty] claim, a jury would have to find that defendants breached the implied warranty of merchantability by manufacturing a medical device that was unsafe in its federally approved design or manufacture. … Such a claim falls squarely within the MDA's preemption provision." Horowitz v. Stryker Corp., 613 F. Supp. 2d 271, 284-85 (E.D.N.Y. 2009). Despite this clear state of the law, Plaintiff's breach of implied warranty claim does just that: it alleges that HOC breached the implied warranty of merchantability because the CerviCore™ "is not of average quality …, is not fit for its ordinary purpose and use as a medical device, was not labeled in a way to warn Ms. Moneymaker … of its grave dangers, and did not conform to its marketing, packaging, and labeling promises of being safe for use in a human body." (FAC at ¶ 254.)

3. Negligence Claims are Expressly Preempted.

Negligence claims are also expressly preempted by the MDA. If a jury were to find against the manufacturer and determine that it was negligent in the manufacture, design, or warning of an IDE device, the jury would, in effect, conclude that the FDA "got it wrong" when it determined that the device was safe and effective. See Horowitz, 613 F. Supp. 2d at 283 ("for plaintiff to be successful in her negligence/recklessness claim a jury would have to find that the FDA requirements themselves were deficient."). Once again, Plaintiff's negligence and gross negligence claims are straightforward state law claims that merely challenge the safety and effectiveness of the CerviCore™. (See, e.g., FAC at ¶ 218.)

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[9] Cf. Ali, 2012 U.S. Dist. LEXIS 121417, at *51 (finding failure to warn claim preempted).

There is no dispute that the CerviCore™ device at issue in this litigation was approved for and was undergoing a clinical trial to determine its safety and effectiveness. Yet Plaintiff sets forth a litany of allegations in support of her strict liability, breach of implied warranty and negligence claims, all of which improperly take issue with the safety and effectiveness of the CerviCore™ in its design, manufacture and warnings. To allow these state law claims to proceed would impose different or additional requirements on the CerviCore™ that are expressly prohibited by the MDA, and would thwart the important public policy supporting discovery and development of new products. See Gile, 22 F.3d at 546.

B. Plaintiff's Breach of Express Warranty Claim Is Preempted By the MDA.

Plaintiff also alleges that HOC "made express warranties to Ms. Moneymaker in the original consent agreements and the addenda to those". (FAC at ¶ 248.) This breach of express warranty claim is also preempted by the MDA pursuant to the rationale set forth in Riegel.

Advertising, promotional materials, and product labeling for PMA devices, and any subsequent changes thereto, are specifically approved through the PMA process. The Supreme Court explicitly held that any such challenges to a PMA device's advertising, promotional materials, and labeling are preempted because they also undergo the rigorous PMA approval process. See Riegel, 128 S. Ct. at 1011. The Court also held that claims challenging the safety and effectiveness of Class III PMA medical devices are preempted. See id. at 1006-07.

Various courts -- including this very Court and others within the Fourth Circuit -- have dismissed breach of express warranty claims regarding the safety and effectiveness of, and/or relating to the advertising, promotional materials, and labeling of, PMA devices. See, e.g., Ali, 2012 U.S. Dist. LEXIS 121417, at *44-*50; Adkins, 2008 U.S. Dist. LEXIS 123843, at *5.[10]

[10] See also In re Medtronic, 623 F.3d at 1207-08; Anthony v. Stryker Corp., 2010 U.S. Dist. LEXIS 31031 (N.D. Ohio Mar. 31, 2010); Yost v. Stryker Corp., 2010 U.S. Dist. LEXIS 27079, at *9-11 (M.D. Fla. Mar. 23, 2010); Riley v. Cordis Corp., 625 F. Supp. 2d 769, 787-88 (D. Minn. 2009); Horowitz, 613 F. Supp. 2d at 285-86; Parker v. Stryker Corp., 584 F. Supp. 2d 1298, 1303 (D. Colo. 2008); Clark v. Medtronic, Inc., 572 F. Supp. 2d 1090, 1095 (D. Minn. 2008); Lake v. Kardjian, 874 N.Y.S.2d 751, 754-55 (Sup. Ct. 2008).

In In re Medtronic, the Eighth Circuit affirmed the dismissal of plaintiffs' breach of express warranty claim, which alleged that the defendant expressly warranted that the PMA devices at issue "'were safe, effective, fit and proper for their intended use'", noting:

> To succeed on the express warranty claim asserted in this case, Plaintiffs must persuade a jury that [the devices] were not safe and effective, a finding that would be contrary to the FDA's approval of the PMA supplement. … The district court correctly concluded that this express warranty claim interferes with the FDA's regulation of Class III medical devices and is therefore conflict preempted.

623 F.3d at 1207-08. Moreover, as this Court has held, breach of express warranty claims that are premised upon FDA-approved advertising, promotional materials, or labeling are also expressly preempted by the MDA. See Ali, 2102 U.S. Dist. LEXIS 121417, at *46. Such claims "would contradict the FDA's determination that the representations made on the label were adequate and appropriate and, thus, impose requirements different from or in addition to the federal requirements." Parker, 584 F. Supp. 2d at 1303.

The only way to avoid preemption of an express warranty claim is to "'establish[] a contractual obligation voluntarily entered into by the manufacturer,'" which could be done by "'identify[ing] specific representations of the manufacturer which *exceed the scope* of the FDA approved statements.'" Ali, 2012 U.S. Dist. LEXIS 121417, at *48 (quoting Horowitz, 613 F. Supp. 2d at 285) (emphasis added).

In the IDE context, express warranty claims are similarly preempted:

> Express representations made about investigational devices are subject to comprehensive FDA regulation. For example, 21 C.F.R. § 812.5 mandates the contents of investigational device labels; § 812.7 prevents the commercialization and promotion of investigational devices, and prohibits any representation that "an investigational device is safe or effective for the purposes for which it is being investigated"; and § 812.25(f) requires submission of all investigational device labeling to the FDA for approval. Thus, the representations that can, cannot and must be made about an investigational device are all determined by the FDA.

Martin, 105 F.3d at 1100-01. Additionally, during the application process, the manufacturer must submit to the FDA for prior approval the consent form to be signed by the study participants. See 21 C.F.R. § 812.25(g). Thus, the FDA has complete oversight of the manufacturer's representations regarding IDE devices.

Plaintiff premises her breach of express warranty claim entirely upon six alleged express warranties that Plaintiff *explicitly* claims were "*in the original consent agreements and the addenda to those*". (FAC at ¶ 256 (emphasis added).) But the "original consent agreements and the addenda to those" were specifically reviewed and approved by the FDA, and any claim challenging the contents of the consent agreement and its addenda are, thus, expressly preempted by the MDA. Accordingly, Plaintiff's breach of express warranty claim must be dismissed.

C. Plaintiff's Fraudulent Concealment, Fraudulent Misrepresentation and Negligent Misrepresentation Claims Are Preempted By the MDA.

Plaintiff claims that HOC had a duty to "disclose" and "accurately represent certain material facts", including "the true risks and dangers posed by CerviCore, the adverse events resulting from CerviCore, the substandard operating conditions in their plants, the use of OP-1 putty, and other negative information", but fraudulently and negligently failed to do so and "misrepresented CerviCore's safety to Ms. Moneymaker". (FAC at ¶¶ 228-242.)

Plaintiff makes these allegations despite the fact that FDA regulations clearly provide for the close FDA oversight of *all labeling and representations* regarding IDE devices. Notably, the label on an investigational device must bear a warning that the device is for investigational purposes only and must describe "all relevant contraindications, hazards, adverse effects, interfering substances or devices, warnings and precautions." 21 C.F.R. § 812.5(a). During the application process, the manufacturer must submit the label to the FDA for review prior to use of the label. 21 C.F.R. § 812.25(f). The manufacturer must also submit for approval the consent form to be signed by the study participant. 21 C.F.R. § 812.25(g). As with the PMA process at issue in Riegel, the FDA regulates the entirety of the product labeling and the representations that can, cannot and must be made in connection with all investigational medical devices. See Martin, 105 F.3d at 1100-01. Because Plaintiff's fraud claims take issue with the label,

representations made regarding the CerviCore™, and the clinical trial, these claims are preempted for the same reasons that the express warranty claim is preempted. See Ali, 2012 U.S. LEXIS 121417, at *50-55 (finding fraud and misrepresentation claims preempted).

D. Plaintiff's Infliction of Emotional Distress Claim is Preempted.

Plaintiff alleges that HOC "intentionally caused, or recklessly disregarded the risks of causing, … emotional distress" or "was negligent in causing Ms. Moneymaker's emotional distress". (FAC at ¶¶ 263-264.) Although penned as a claim for emotional distress, the crux of Plaintiff's claim, as explicitly set forth in Count XII, is that CerviCore™ was defectively manufactured and that HOC failed to warn about, fraudulently concealed, and fraudulently misrepresented information regarding CerviCore™. (See FAC at ¶ 260.)

Plaintiff's infliction of emotional distress claim is simply a repackaged claim for defective manufacture, failure to warn, fraudulent concealment, and fraudulent misrepresentation wherein Plaintiff seeks damages for the resultant emotional distress that she allegedly suffered. Because such claims are preempted by the MDA, Count XII of the FAC must also be dismissed.

E. Plaintiff's Breach of Contract Claim is Expressly Preempted.

Plaintiff's claim for "Breach of Contract" is also a cause of action in name only. This claim is simply another cause of action for alternative relief that is premised upon allegations challenging the safety and effectiveness of the CerviCore™ and its underlying clinical study. The breach of contract claim alleges that HOC breached its contract -- specifically, the informed consent -- by failing to provide Ms. Moneymaker "with necessary medical care" and continued monitoring of "the study participants and their health". (FAC at ¶¶ 245-246.)

First, the informed consent is specifically reviewed and approved by the FDA during the IDE application process. See 21 C.F.R. § 812.25(g). Accordingly, any claims regarding the FDA-approved informed consent are clearly preempted by the MDA. Additionally, state law claims challenging the safety and efficacy of the manner in which HOC conducted the FDA-approved study regarding the CerviCore™ -- such as Plaintiff's allegations of failure to provide medical care and continued medical monitoring -- are clearly preempted by the MDA. Cf. Desabio v. Howmedica Osteonics Corp., 2011 U.S. Dist. LEXIS 103288, at *21 (W.D.N.Y.

Sept. 13, 2011) ("a finding that a defendant violated state law by not living up to FDA-approved promises would necessarily conflict with the FDA's determination that the label was not false or misleading."). Therefore, Plaintiff's claim for breach of contract, is preempted by the MDA. See Millman v. Medtronic, 2015 U.S. Dist. LEXIS 21750 (D.N.J. Feb. 24, 2015) (dismissing, inter alia, breach of contract claim because it is a theory "of liability relating to the safety or effectiveness of the device and seek[s] to impose additional requirements upon Defendant").

F. Plaintiff Has Not Alleged "Parallel" Claims.

Riegel's final paragraph recognizes a narrow exception that permits a state damages remedy to be "parallel" and not preempted, but *only* if it does not impose requirements that differ from or add to requirements imposed by federal law. See 128 S. Ct. at 1011. State law remedies may be available for certain "claims premised on a violation of FDA regulations…." Id. However, such parallel claims are *very rare* and *cannot* challenge the safety or effectiveness of an IDE device. See id. at 1011. Juxtaposed with the parallel claim exception is well-settled law that a plaintiff does not possess a separate, private right of action based upon alleged violations of the FDCA, as such claims are impliedly preempted by 21 U.S.C. § 337(a). See Buckman, 121 S. Ct. at 1018 n.4. Indeed, "'Riegel and Buckman create a narrow gap through which a plaintiff's state-law claim must fit if it is to escape express or implied preemption.'" In re Medtronic, 623 F.3d at 1204 (quoting Riley, 625 F. Supp. 2d at 777).

In Ali, this very Court espoused the standard applicable to stating a viable parallel claim:

> [T]o adequately plead a parallel state-law claim and avoid § 360k(a) preemption, a plaintiff must allege a violation of federal regulations with sufficient facts to render the alleged violation plausible under Twombly and Iqbal. … [C]onclusory allegations that the defendant violated FDA regulations in the manufacture, labeling, or marketing of the premarket approved medical device are insufficient to state a parallel state-law claim and thereby avoid preemption under § 360k(a).

2102 U.S. Dist. LEXIS 121417, at *18-*19 (citations omitted). In the IDE context, a proper allegation of a parallel claim contains "an allegation that the design, manufacture, or marketing of the … device deviated in some way from the specifications approved for clinical trials by the FDA." Burgos, 2010 U.S. Dist. LEXIS 125924, at *10.

Plaintiff's claims are the precise type that the Supreme Court and this Court intended would be preempted in Riegel, Ali, and Buckman. Plaintiff merely challenges the safety and effectiveness of the CerviCore™ by alleging an injury that resulted from a purportedly defective device. Plaintiff has not asserted a viable parallel claim by repeatedly making unsupported allegations that the CerviCore™ deviated from the scope of its IDE, citing to inapplicable and non-specific CGMPs, citing to irrelevant warning letters, or alleging that the CerviCore™ was adulterated. Such tactics have been considered and rejected by numerous courts.

1. Unsupported Allegations of Violations of IDE Requirements Do Not Convert Plaintiff's State Law Claims into Parallel Claims.

As noted above, to state the rare parallel claim that survives express MDA preemption and Twombly and Iqbal scrutiny, a plaintiff's initial pleading must "allege a violation of federal regulations with sufficient facts to render the alleged violation plausible". Ali, 2012 U.S. Dist. LEXIS 121417, at *18. In the IDE context, a plaintiff must allege the specific way in which the "device deviated … from the specifications approved for clinical trials by the FDA." Burgos, 2010 U.S. Dist. LEXIS 125924, at *10. Simply stated, Plaintiff has not done so here.

a. Plaintiff Fails to Support Her Claim That HOC Operated Outside of the Scope of the IDE.

Plaintiff makes the following unsupported allegations: HOC "operated outside the scope of any IDE" and "was conducting human trials improperly and in violation of the law". (FAC at ¶¶ 164(a), 218(b), 225(a), 236, 241, 248(a).) These bald, conclusory allegations do not provide the requisite pleading particulars required by the Supreme Court in Twombly and Iqbal.

b. Plaintiff's Claim Regarding the CerviCore™'s Chemical Composition Is Not Plausible.

Plaintiff states that "CerviCore's chemical composition is other than what Howmedica told study participants and the FDA." (FAC ¶ 41.) However, a closer look into the actual allegations following this claim demonstrates that Plaintiff lacks any basis for such claim. First, Plaintiff relies upon a "wallet card" of a Ms. Donna Zaretzka and a "Consent to Participate in a Research Study" of a Ms. Colleen Jaeger. (See id. at ¶¶ 43-44.) Notably, Plaintiff fails to allege any facts to support her inference that the information on either of these items is inaccurate,

contradictory or in violation of the IDE (both note the composition of the device, and one also refers to a plasma spray coating). In any event, neither Ms. Zaretzka nor Ms. Jaeger is a party to this action, and, as such, any allegations regarding these individuals are not only irrelevant to Plaintiff's specific claims before this Court, but also prejudicial to HOC.[11] Nonetheless, Plaintiff's citation to information contained in information read by two non-parties does not make it plausible that HOC withheld information regarding the chemical composition of the device from, or provided false information in this regard to, the FDA or Plaintiff.

Second, Plaintiff relies upon the alleged contribution of three physicians to a chapter in an 816-page book to support her "chemical composition" claim. (See FAC at ¶¶ 41, 45.) Plaintiff references a *single sentence* regarding a particular metal allergy being a contraindication for the use of the device. (See id. at ¶ 45.) Yet, nowhere does Plaintiff allege that *HOC* made any representations in this book. Reliance upon a single, out-of-context sentence from an 816-page book that was authored by three non-party physicians cannot plausibly support a claim that the chemical composition of *Plaintiff's* device was other than what HOC disclosed to the FDA and Plaintiff.

Finally, Plaintiff relies upon an advertisement in a program for the SAS International Society for the Advancement of Spine Surgery that HOC allegedly purchased to support their claim regarding HOC's disclosure of the chemical composition of the device. (See id. at ¶¶ 42, 46.) Once again, Plaintiff offers no plausible facts to support the inference that the information is inaccurate. Regardless, Plaintiff cannot come close to meeting Twombly and Iqbal's plausibility standard by relying upon an alleged advertisement in a program that was disseminated at a conference to support the contention that HOC allegedly withheld information from *the FDA and Plaintiff*.[12]

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[11] Plaintiff's FAC is replete with allegations regarding individuals who are not parties to this litigation, and HOC is also moving to strike all such irrelevant and prejudicial allegations.

[12] Plaintiff's allegations regarding the chemical composition of the CerviCore™ are highly suspect and do not support a viable parallel claim because Plaintiff claims that her device *shifted*. (See FAC at ¶ 156.) Nowhere in the FAC does Plaintiff allege any sort of injury that could have resulted from exposure to the chemical composition of the device.

c. Plaintiff's Failure Rate Claims Are Implausible.

Like Plaintiff's chemical composition claims, Plaintiff's allegation that HOC failed to accurately report the failure rates of the CerviCore™ to the FDA and Plaintiff is highly implausible and does not support a parallel claim. In support of her specious claim, Plaintiff relies upon a failure rate set forth in a 2010 journal article in The Spine Journal written by four physicians regarding results from four of the CerviCore™ IDE study sites. (See id. at ¶ 92.) Plaintiff then challenges the failure rate "reported" by these four physicians by doing her own "calculations" and "computing" the alleged failure rate by the purported failure of the devices of five non-party individuals. (See id.) Plaintiff also challenges the failure rate noted in the journal article by relying upon statements allegedly made by an HOC "field representative" to another non-party individual having nothing to do with Plaintiff. (See id. at ¶ 93.)

Notably, at no time does Plaintiff plead any factual allegations as to how HOC allegedly misled the FDA regarding failure rates of the device, and, thus, there are no factual allegations regarding any possible violation of the FDCA. Moreover, at no time does Plaintiff make any factual allegations regarding how HOC misled her regarding the failure rate of her particular device. It is, in fact, impossible that any "inaccurate" failure rate listed in a September 2010 journal article affected Plaintiff's decision to participate in the CerviCore™ clinical trial and receive her specific device more than four years *earlier* in May or June 2006 (see id. at ¶ 155).

Accordingly, Plaintiff's manufactured claim regarding the purportedly inaccurate reporting of the failure rate of the CerviCore™ cannot transform her claims regarding the safety and effectiveness of the device into a viable parallel claim.

d. Plaintiff's Claims Regarding OP-1 Are Implausible.

Plaintiff's allegations regarding OP-1 are based upon pure speculation, are highly implausible, and do not support a viable parallel claim. First, Plaintiff relies upon a claim that the FDA found that "Stryker Biotech had illegally entered into contracts with clinical investigators to use OP-1 in combination with some investigational device study" and base this claim upon a warning letter issued to *Stryker Biotech* regarding a *Massachusetts manufacturing facility*. (See FAC at ¶ 101.) Notably, however, Stryker Biotech is not a party to this litigation

nor did it manufacture the CerviCore™, and Plaintiff admits that the CerviCore™ was *not* manufactured in Massachusetts. (See id. at ¶ 55.) Second, Plaintiff refers to bone mass growth allegedly suffered by two non-parties, but provides no information regarding causation and no support whatsoever for any inference that the bone growth was related to OP-1, *which was not used in conjunction with CerviCore™*. (See id. at ¶¶ 104-105.) Importantly, at no time does Plaintiff claim that she suffered from "significant, spontaneous bone growth", which Plaintiff alleges is the effect associated with utilizing OP-1. (See id. at ¶¶ 103, 155-162.)

It is highly suspect for Plaintiff to suggest that an alleged FDA finding regarding a non-party, a manufacturing facility not at issue in this litigation, and injuries suffered by non-parties make it in any way plausible that HOC violated IDE requirements by using a product *not even approved for use in conjunction with the CerviCore™ by the FDA*, that Plaintiff herself received this product, and that the purported use of this product caused her injuries. This practice is simply desperate pleading, not *plausible* pleading.

Accordingly, Plaintiff has failed to state a parallel claim.[13]

2. Alleged Violations of CGMPs Do Not Convert Plaintiff's State Law Claims into Parallel Claims.

It is beyond dispute that CGMPs are not applicable to IDE devices: "Once the device is approved under the IDE, the device is exempted from, among other things, compliance with performance standards and good manufacturing practice requirements." Martin, 105 F.3d at 1096 (citing 21 C.F.R. § 812.1(a)). It is, therefore, impossible to premise a parallel claim regarding an IDE device upon alleged violations of CGMPs. Accordingly, Plaintiff's attempt to premise her claims upon alleged violations of 21 C.F.R. §§ 820.100(a)(1), (a)(3) and (a)(4) and the entire Part 820 of the CFR (see FAC at ¶¶ 77, 197) is nonviable.

[13] Plaintiff has similarly failed to state a parallel claim by including allegations regarding exposure to dangerous metals due to the design of the product, failure to monitor metal levels of certain study participants, and failure to provide medical care (see FAC at ¶¶ 51-69, 82-90, 107-121) because each challenges the safety of the device and the clinical trial of the device, and fails to allege even a single violation of FDA regulations. Additionally, Plaintiff's allegations regarding the exposure to dangerous metals and failure to monitor metal levels are dubious and do not support a viable parallel claim because Plaintiff claims that her device *shifted*.

Yet, even if CGMPs were applicable to IDE devices, which they are not, they still cannot form the basis of a successful parallel claim. Per Riegel, specificity lies at the heart of the PMA and IDE express preemption analysis. See Riegel, 128 S. Ct. at 1007 ("Unlike general labeling duties, premarket approval is specific to individual devices."). Accordingly, general allegations of non-specific CGMPs applicable to *all* devices and *all* device manufacturers are insufficient to withstand express preemption by the MDA.

This need for specificity has been emphasized by the Fourth Circuit. In Walker v. Medtronic, Inc., the Fourth Circuit rejected the plaintiff's attempt to state a parallel claim, and affirmed dismissal of the action, wherein the plaintiff alleged that a device failed to comply with the terms of its PMA. See 670 F.3d 569, 576, 581 (4th Cir. 2012). The plaintiff therein attempted to rely upon a technical specification regarding the actual device's output -- something much more specific than the CGMPs relied upon in the instant action. The Fourth Circuit held that even this was an insufficient basis for a parallel claim. Id. at 579. As explained by the Court, the FDA may promulgate a formal "performance standard" to which a device must adhere as a condition of its PMA, and the creation of a performance standard is the only mechanism for creating a binding, ongoing performance requirement for a medical device under the MDA. Id. at 578-79. Merely because a technical specification is included in a device's PMA does not indicate that the specification imposes a binding requirement. Id. at 579 n.5. The Court noted that if it were to treat a technical specification as a "requirement", this would impose a heightened standard on the manufacturer, beyond that promulgated by the FDA, which is impermissible under Riegel. Id. at 578. The Court further noted that such a holding would upend the careful construct Congress created in the MDA, balancing potential rewards of such devices following the rigorous PMA process against the cost of preempting common law claims based upon standards different than those imposed by the FDA. Id. at 578-79. If, as the Fourth Circuit has recognized, premising a claim upon a deviation from a technical specification set forth in the PMA materials of a device is insufficient to state a parallel claim, then premising a claim upon violations of generally applicable CGMPs -- which are statutorily *in*applicable to

IDE devices -- must certainly be deemed insufficient to state a parallel claim. Therefore, in accordance with the Fourth Circuit's reasoning in Walker, this Court should deem Plaintiff's reliance on alleged violations of CGMPs insufficient to state a parallel claim.

Significantly, courts around the country have repeatedly agreed and held that a plaintiff's allegations of violations of CGMPs are insufficient to evade preemption: "because these [CGMP] regulations do not address the manufacturing of the specific device at issue … they cannot establish the requisite standard of care that a particular manufacturer must meet". Gross v. Stryker Corp., 858 F. Supp. 2d 466, 493-97 (W.D. Pa. 2012).[14] In Ilarraza v. Medtronic, Inc., the Eastern District of New York concluded that the plaintiff failed to state a parallel claim "because no regulation relied upon refers *specifically* to the medical device at issue here. Instead, each regulation cited is nothing more than a general statement of a CGMP[]." 677 F. Supp. 2d at 588 (emphasis added). The court explained that CGMPs "are purposefully broad so as to apply to a broad range of medical devices." Id. Specifically, because CGMPs

> are open to a particular manufacturer's interpretation, allowing them to serve as a basis for a [parallel] claim would lead to differing safety requirements that might emanate from various lawsuits. This would necessarily result in the imposition of standards that are 'different from, or in addition to' those imposed by the MDA - precisely the result that the MDA preemption provision seeks to prevent.

Id. Therefore, when a plaintiff relies upon CGMPs to support a purported parallel claim, "preemption bars the claim."[15] Id.

Plaintiff here relies upon a barebones allegation of violations of the *entire* Part of the Code of Federal Regulations addressing each and every CGMP to support her purported parallel claim. (See FAC at ¶ 197(a).) 21 C.F.R. § 820, which contains 31 separate sections, is

[14] See also Ilarraza v. Medtronic, Inc., 677 F. Supp. 2d 582, 588 (E.D.N.Y. 2009); Horowitz, 613 F. Supp. 2d at 284; In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig., 592 F. Supp. 2d 1147, 1157 (D. Minn. 2009) ("Medtronic MDL"), aff'd In re Medtronic, 623 F.3d 1200.

[15] The Ilarraza court further held that because of the "broad nature of the federal regulations relied upon," plaintiff's allegations could not withstand Twombly scrutiny: "Where, as here, the plaintiff has done nothing more tha[n] recite unsupported violations of general regulations, and fails to tie such allegations to the injuries alleged, the complaint is properly dismissed." Id.

applicable to *all* manufacturers of *all* medical devices. This entire C.F.R. Part is the type of broad, non-specific regulation applicable to all medical devices and manufacturers that fails to convert a state law claim for safety and effectiveness into a parallel claim.

Additionally, Plaintiff pleads the violation of three subsections of 21 C.F.R. § 820.100(a)[16] that she merely lifted from the text of an irrelevant warning letter (see Section I(F)(3), infra).[17] (See FAC at ¶¶ 77, 197(c).) Significantly, that portion of the warning letter was with regard to *ceramic hip* implant components, and had *nothing* to do with CerviCore™.

"Allowing a plaintiff to plead non-specific regulations as a basis for a parallel claim is inconsistent with the Supreme Court's reasoning in Riegel, as well as the pleading requirements articulated in Twombly [and] Iqbal." Gross, 858 F. Supp. 2d at 495. Plaintiff here draws no connection in the FAC between HOC's alleged CGMP violations and her claim that her particular CerviCore™ purportedly caused her alleged injuries. Accordingly, Plaintiff has not asserted a parallel claim, and, thus, cannot escape express preemption of her causes of action.

3. Plaintiff's Citation to Irrelevant Warning Letters Does Not Convert Her Expressly Preempted Claims into Parallel Claims.

Courts confronted with citations of warning letters, and the alleged violations of federal regulations cited therein, have repeatedly held that such references are not a basis for a parallel claim because: (1) "[t]he warning letter … do[es] not … establish any duty that [defendant] had to Plaintiff in manufacturing the" device, Gross, 858 F. Supp. 2d at 497; (2) the letter does not "indicate that [defendant] breached any alleged duty by failing to comply with the PMA process," id.; (3) "Plaintiff's generalized allegations cannot withstand preemption because they fail to establish the necessary link between defendants' federal violations and her alleged causes of action," Horowitz, 613 F. Supp. 2d at 280; (4) "such letters do not provide the necessary

[16] Subsection 820.100(a) only generally requires *every* manufacturer of *every* medical device to create its own individual procedures "for implementing corrective and preventative action".

[17] Notably, this very Court has held that where, as here, the language in a complaint "closely tracks the language of" the CGMPs allegedly violated, such simplistic "recitations of regulatory language are no more entitled to the assumption of truth than pure legal conclusions." Ali, 2012 U.S. Dist. LEXIS 121417, at *33.

connection to the specific [device] at issue in this case," id.; (5) "plaintiff nevertheless cannot escape preemption by reference to provisions of the FDCA that govern the sale of adulterated and misbranded devices because there is no private right of action under the FDCA," Parker, 584 F. Supp. 2d at 1302; and (6) "nowhere does plaintiff's complaint provide any factual detail to substantiate that crucial allegation," id.

Plaintiff here relies upon information contained in three irrelevant warning letters in support of her claim that the CerviCore™ was "adulterated and contaminated by Howmedica's manufacturing processes". (FAC at ¶¶ 70-81.) However, the allegations regarding the warning letters, and alleged violations of non-specific federal regulations identified therein regarding devices other than the CerviCore™, do not relate to Plaintiff's CerviCore™ or her alleged injury, and, thus, do not satisfy Twombly and Iqbal scrutiny. See Gross, 858 F. Supp. 2d at 495-97.

Plaintiff not only fails to explain, but it is impossible for her to explain, how the terms and purported conclusions of these three warning letters issued to HOC and non-parties Stryker Ireland and Stryker Biotech apply to Plaintiff's specific device or how any issues identified therein allegedly caused Plaintiff's purported injuries and damages. As recognized by this Court, such a failure to link allegations of federal regulation violations cited in those warning letters to Plaintiff's specific device and injuries is fatal to her claims. See Ali, 2012 U.S. Dist. LEXIS 121417, at *23-24. Accordingly, Plaintiff's repeated citation to and quotation from these three warning letters and reliance upon the violations cited therein do not plausibly allege that the CerviCore™ was "adulterated and contaminated by [HOC's] manufacturing processes", and are insufficient to convert her state law claims into parallel claims.

4. The FDCA Does Not Provide for a Private Right of Action to Enforce the MDA.

Plaintiff attempts to save her claims from preemption by alleging that, inter alia, (1) HOC violated non-specific federal regulations, (2) the CerviCore™ was adulterated, and (3) HOC committed fraud on the FDA. (See, e.g., FAC at ¶¶ 41, 70, 77, 91, 164(a), 197(c).) In addition to failing to save Plaintiff's claim from express preemption, as explained in detail, supra,

Plaintiff's attempt to save her claims also fails because it is well settled that allegations of FDCA violations, adulteration and fraud on the FDA are impliedly preempted pursuant to Buckman.

First, the FDCA does not provide a private right of action for enforcement of the MDA, see Buckman, 121 S. Ct. at 1018 n.4, and "[p]laintiffs cannot make an end run around this rule by recasting violations of the FDCA as violations of state common law," Medtronic MDL, 592 F. Supp. 2d at 1161 (citations omitted), aff'd In re Medtronic, 623 F.3d 1200. Second, claims of adulteration cannot serve as a basis for a viable parallel claim because such claims are impliedly preempted pursuant to Buckman.[18] Finally, it is beyond dispute that claims of fraud on the FDA are impliedly preempted. See Buckman, 121 S. Ct. 1012. Accordingly, not only are Plaintiff's claims regarding the CerviCore™ expressly preempted by Riegel, but her claims of violations of federal regulations, adulteration, and fraud on the FDA are impliedly preempted by Buckman.

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Therefore, each and every claim in the FAC is preempted, and must be dismissed.[19]

II. THE APPLICABLE STATUTES OF LIMITATION EXPIRED ON EACH OF PLAINTIFF'S CAUSES OF ACTION

A. Plaintiff's Negligence, Breach of Warranty, Strict Liability, and Emotional Distress Claims Are Time-Barred.

Plaintiff's personal injury causes of action accrued, and the statute of limitations began to run, "on the date the injury [was] sustained … and not when the resulting damage [was] discovered." See Va. Code § 8.01-230. Her personal injury claims should, therefore, have been filed no later than two years after her alleged injury. See Va. Code § 8.01-243(A) ("Unless otherwise provided in this section or by other statute, every action for personal injuries, *whatever*

[18] See Cornwell v. Stryker Corp., 2010 U.S. Dist. LEXIS 116824, *11 (D. Idaho Nov. 1, 2010); Lewkut v. Stryker Corp., 724 F. Supp. 2d 648, 659-60 (S.D. Tex. 2010); Medtronic MDL, 592 F. Supp. 2d at 1163, n.19, aff'd In re Medtronic, 623 F.3d 1200; Parker, 584 F. Supp. 2d at 1301.

[19] The final cause of action in the FAC is a catch-all claim, wherein Plaintiff solely "pleads violations of Virginia state statutory and common law remedies where Virginia has adopted state statutory or common law remedies to replace the common law theories espoused in Counts I through XIII." (FAC at ¶ 267.) This cause of action is expressly and impliedly preempted for the very reasons that each of the preceding claims are preempted.

the theory of recovery, … shall be brought within two years after the cause of action accrues") (emphasis added); Nunnally v. Artis, 492 S.E.2d 126, 127 (Va. 1997). Whether based upon legal theories of negligence, strict liability, breach of express or implied warranty, or emotional distress, each count of the FAC asserts a claim for money damages for physical injuries.[20]

The FAC alleges the following material facts about Plaintiff's surgery:

> (1) "Plaintiff … had a CerviCore unit implanted by Dr. Harold F. Young, MD in *May or June, 2006....*" (FAC at ¶ 155 (emphasis added).)
>
> (2) "At a six week visit, Dr. Young ordered an X-Ray, found the CerviCore had shifted, and immediately scheduled a removal surgery." (Id. at ¶ 156.)
>
> (3) On July 6, 2006, "Dr. Young reported the adverse event to the FDA's MAUDE … Database" (id. at ¶ 157), wherein he noted, inter alia, that post-implantation: (1) an "X-ray revealed that artificial disc was dislodged"; (2) the "patient stated that she had difficulty swallowing when neck was fully extended"; and (3) the "patient returned … for cervicore adr removal" the following day. (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/detail.cfm?mdrfoi_id=739251, cited in FAC at ¶ 157 (emphasis added.)

It is clear, per Plaintiff's own allegations, that the allegedly defective CerviCore™ device had been removed, and the statute of limitations accrued, no later than July 6, 2006. However, Plaintiff waited to file her original Complaint until April 11, 2014, long after Virginia's two-year, personal injury statute of limitations expired in 2008.

Importantly, although the symptoms of Plaintiff's injury might have been delayed, the alleged injury had definitively occurred by July 6, 2006. When an implanted medical device allegedly causes the plaintiff's injury, the accrual of the cause of action is "necessarily fix[ed] … at the time of implantation, even though more substantial injury may have occurred later…." Smith v. Danek, 47 F. Supp. 2d 698, 701 (W.D. Va. 1998). Thus, Plaintiff's claims for strict

[20] See Moore v. Allied Chemical Corp., 480 F. Supp. 364, 369 (E.D. Va. 1979); Tyler v. R.R. St. & Co., 322 F. Supp. 541, 543 (E.D. Va. 1971); Friedman v. Peoples Serv. Drug Stores, Inc., 160 S.E.2d 563, 565 (Va. 1968). Even if Virginia recognized strict liability claims, which it does not, they would also be governed by the two year statute of limitations provided in Va. Code § 8.01-243(A), which applies to "every action for personal injuries, whatever the theory of recovery."

liability, negligence, gross negligence, breach of express and implied warranty, and emotional distress, all of which are claims for damages for the same personal injury, must be dismissed with prejudice because they are all barred by the applicable statute of limitations.

B. Fraud Claims are Barred by Virginia's Two-Year Statute of Limitations.

The statute of limitations governing Plaintiff's fraud claim is two years. See Va. Code § 8.01-243(A). Fraud claims accrue when the alleged misconduct "is discovered or by the exercise of due diligence reasonably should have been discovered." Va. Code § 8.01-249(1).

Plaintiff alleges that during a six-week follow up visit after her receipt of the CerviCore™, Dr. Young discovered that the device had shifted and scheduled "immediate" surgery to remove the device. (See FAC at ¶¶ 156-158.) The device was removed the next day, and Dr. Young returned the device to HOC and filed an Adverse Event Report with the FDA. (See https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/detail.cfm?mdrfoi_id=739251, cited in FAC at ¶ 157; see also FAC at ¶ 158.) Those facts put Plaintiff on notice no later than July 2006 that there might have been something wrong with the CerviCore™ device. Indeed, Plaintiff alleges that books, articles, studies, and FDA investigations were published between 2007 and 2011 that revealed the "truth" about CerviCore. (See FAC at ¶ 45 (citing *2008* book, James Yue, *et. al.*, MOTION PRESERVATION SURGERY OF THE SPINE: ADVANCED TECHNIQUES AND CONTROVERSIES, p. 238, Saunders, 2008); id. at ¶ 46 (referencing to *2011* advertisement; id. at ¶¶ 71, 72, 76 (citing warnings letters issued by the FDA in *2007* and *2008*.)

Had Plaintiff exercised due diligence, she should have discovered HOC's alleged misrepresentations based on such publicly available information no later than 2011. See Burrell v. Astrazeneca LP, et. al., 2010 Del. Super. LEXIS 393, at *30 n. 72 (Del. Super. Ct. Sept. 20, 2010); cf. Resolution Trust Corp. v. Walde, 856 F. Supp. 281, 289 (E.D. Va. 1994). Plaintiff, however, waited to file her original Complaint until April 11, 2014. Thus, her fraud and misrepresentation claims are all barred by the statute of limitations and must be dismissed.

C. Plaintiff's Breach of Contract Claim Is Barred By the Statute of Limitations.

The statute of limitations is five years for breach of a written contract and three years for breach of an oral contract. See Va. Code § 8.01-246(2) and (4). A contract claim accrues when

the breach occurs "and not when the resulting damage is discovered." See Va. Code § 8.01-230; see also Arrington v. Peoples Sec. Life Ins. Co., 458 S.E.2d 289, 291 (Va. 1995).

A written contract is a contract "which is in writing and *signed by the party to be charged thereby, or by his agent*". Va. Code § 8.01-246 (emphasis added). Plaintiff's breach of contract claim in Count IX is based upon an "informed consent form" that she apparently signed as part of her enrollment in the CerviCore™ study. (See FAC at ¶¶ 122-23, 244-46.) The FAC does not allege that the "informed consent form" was signed by HOC, the "party to be charged thereby", or by any "agent" of HOC. See Va. Code § 8.01-246(2). Thus, the five year statute of limitations applicable to a written contract does not apply. Newport News, H. & O. P. Development Co. v. Newport N.S.R. Co., 32 S.E. 789, 790 (Va. 1899). Rather, the breach of contract claim is governed by the three year statute of limitations. Va. Code § 8.01-246(4).

Plaintiff alleges that HOC breached its contract when it "failed to provide Ms. Moneymaker with necessary medical care." (FAC at ¶ 245.) Plaintiff had surgery to remove the CerviCore device in the summer of 2006. (See id. at ¶¶ 156-157.) HOC then allegedly failed to provide her with any of the promised medical care and thereafter "abandoned her." (See id. at ¶¶ 107-108, 117, 120.) Indeed, the FAC specifically alleges that HOC anticipatorily repudiated its alleged promise of future medical care by "abandoning" her. (See id. at ¶ 120.) Thus, any contract claim accrued in the summer of 2006. Caudill v Wise Rambler, 168 S.E. 2d 257, 260 (1969) (cause of action accrues when breach occurs even though the actual or substantial damages do not occur until later). Accordingly, Plaintiff should have brought her breach of contract claim by the summer of 2009, thereby rendering her actual breach of contract claim, filed on April, 11, 2014, barred by statute of limitations pursuant to Va. Code § 8.01-246(4), and must be dismissed with prejudice.[21]

[21] Even if Plaintiff had adequately alleged breach of a written contract, her breach of contract claim would nevertheless be barred by the five-year statute of limitations pursuant to Va. Code § 8.01-246(2), as the statute of limitations would have expired no later than the summer of 2011.

III. VIRGINIA LAW DOES NOT RECOGNIZE STRICT LIABILITY CLAIMS

Virginia "does not permit tort recovery on a strict-liability theory in products-liability cases." Sensenbrenner v. Rust, Orling & Neale, Architects, Inc., 374 S.E.2d 55, 57 n. 4 (Va. 1988). This Court recently reiterated this longstanding state of the law, and held that a plaintiff "cannot state a viable claim for strict liability as to design and manufacturing defects … as well as Defendants' alleged failure to warn." See Sanyal v. Toyota Motor N. Am., Inc., 2015 U.S. Dist. LEXIS 5667, at *5 (E.D. Va. Jan. 15, 2015). Plaintiff's improper attempt to assert such claims clearly fails because they are undisputedly not recognized by Virginia law.

IV. COUNTS VI, VII, VIII, AND XI ARE INADEQUATELY PLED.

A. Counts VI, VII, and VIII Are Not Pled With Particularity.

Fraud claims are subject to a "heightened pleading" standard, which requires a complaint to "state with particularity the circumstances constituting the fraud." Fed. R. Civ. P. 9(b). Thus, the fraud by concealment, fraudulent misrepresentation and negligent misrepresentation claims are subject to Rule 9(b)[22], and Plaintiff must plead "the time, place, and contents of the false representations, as well as the identity of the person making the misrepresentation and what he obtained thereby." Harrison, 176 F.3d at 784 (quotations omitted).

Plaintiff's fraudulent concealment, fraudulent misrepresentation and negligent misrepresentation claims do not come close to meeting the pleading requirements of Rule 9(b). At no point in the FAC does Plaintiff allege the contents of the alleged false representations; the time or place of the alleged fraudulent acts; the identity of the person making the alleged misrepresentations; and what HOC obtained as a result of the alleged fraudulent acts.[23]

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[22] See Chitty v. Liberty Univ., 2013 U.S. Dist. LEXIS 105052, at *5 (W.D. Va. Jul. 25, 2013) (noting that "[a] 'negligent misrepresentation' claim is essentially a 'constructive fraud' claim" and applying Rule 9(b)'s heightened pleading requirement).

[23] For example, the FAC is simply comprised of such conclusory statements as "Howmedica had a duty to accurately represent certain material facts, which include those dangers of which they knew", "[t]hrough its silence and through its statements, Howmedica actively misrepresented CerviCore's safety to [Plaintiff] and other CerviCore recipients", and "Howmedica was negligent in its representations to" Plaintiff (FAC at ¶¶ 234-235, 239-240.)

Notably, Plaintiff effectively admits in the FAC that she cannot plead any particulars regarding fraudulent statements and/or misrepresentations made to her. (See FAC at ¶ 7.) Specifically, Plaintiff pleads in paragraph 7 that although "every plaintiff alleges Howmedica concealed information and misled him or her", she will rely upon "multiple references to her eight former co-plaintiffs' experiences and injuries" to attempt to state her fraud claims.[24] (See id.). These references do not relate to Plaintiff and clearly do not form a basis for Plaintiff to plead a cause of action for fraud. Indeed, nowhere in the FAC does Plaintiff make any allegations of omissions or misrepresentations made to *her*. The failure to link alleged claims of fraud to the Plaintiff is fatal, and Counts VI-VIII must be dismissed.

B. Plaintiff Cannot Maintain A Claim for Breach of Implied Warranty.

Plaintiff attempts to plead a claim for breach of implied warranty of merchantability[25] (see FAC at ¶¶ 252-258) even though it is impossible to maintain such a claim regarding an IDE device. Per Section 8.2-314, "a warranty that the goods shall be merchantable is implied in a contract for their sale if the seller is a merchant with respect to goods of that kind. Va. Code Ann. § 8.2-314(1). Of note is the requirement that there be a contract for the *sale* of goods. Indeed, the very definition of "merchantable" is that the goods be "fit for *sale*: *vendible in the market*; or a quality such as will bring the ordinary market price." Black's Law Dictionary, available at thelawdictionary.org/merchantable/ (emphasis added).

Plaintiff cannot claim that her CerviCore™ was "merchantable" or that there was a "contract for the sale" of the device, because Plaintiff received her CerviCore™, an *experimental* device, during a clinical trial. Indeed, the very purpose of the clinical trial was to determine

[24] For example, Plaintiff includes irrelevant and prejudicial allegations regarding Ms. Jaeger's meetings with a study investigator and a HOC field representative and recounts the alleged interaction between Ms. Jaeger and the HOC field representative. (See, e.g., FAC at ¶ 93.)

[25] Although Plaintiff alleges earlier in the FAC in a conclusory fashion that HOC "is bound by implied warranties of … fitness for a particular purpose and breached those" (id. at ¶ 164(l)), nowhere in the remainder of the FAC, much less in the "Breach of Implied Warranty" Count, does Plaintiff make any allegations regarding any purported warranty of fitness for a particular purpose. Rather, this Count is comprised solely of allegations regarding the warranty of merchantability. (See id. at ¶¶ 252-258.)

whether the CerviCore™ was merchantable. Just as "the FDA can hardly be expected to specify the safe and effective design of a device when it is still experimental", Becker, 66 F.3d at 21, it can hardly be expected that HOC impliedly warranted that the CerviCore™ was merchantable when it was still experimental. Accordingly, Plaintiff cannot adequately plead or maintain a cause of action for breach of implied warranty of merchantability.

CONCLUSION

For the foregoing reasons, defendant HOC respectfully requests that the Court enter an Order dismissing Plaintiff's First Amended Complaint with prejudice.

Dated: the 22nd day of April, 2015

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CERTIFICATE OF SERVICE

I hereby certify that on this 22nd day of April, 2015, a true and correct copy of the foregoing pleading or paper was served using the Court's CM/ECF system, with electronic notification of such filing to the following counsel of record:

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